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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,466	01/06/2004	Thomas M. Soukup	H583.104.102	3375

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EXAMINER	
SMITH, FANGEMONIQUE A	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
04/26/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/752,466	SOUKUP ET AL.	
	Examiner	Art Unit	
	Fangemonique Smith	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60,61 and 63-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60, 61 and 63-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on February 09, 2011. Examiner acknowledges the amendment of claims 60 and 80. Claims 60, 61 and 63-99 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

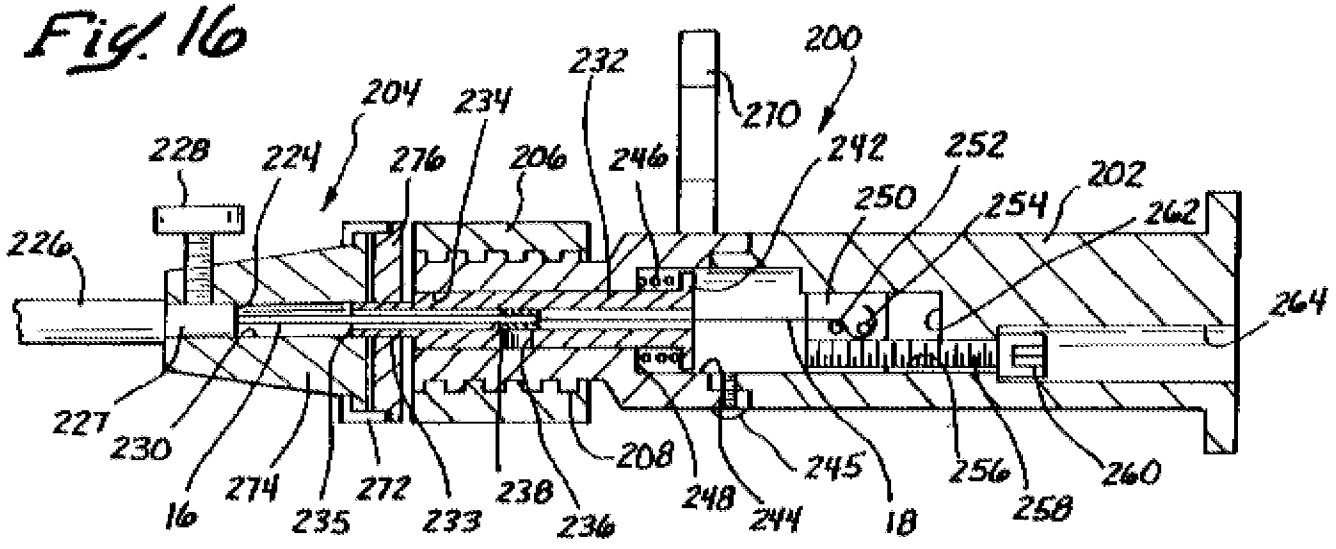
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> .

3. Claims 60, 61, 63, 64, 66, 77-84, 86 and 97-99 are rejected under 35 U.S.C. 103(a) as being anticipated by Cookston et al. (U.S. Patent Number 6,132,390) in view of Lundquist et al. (U.S. Patent Number 6,033,378).

In regard to claims 60, 61, 63, 64, 66, 77-84, 86 and 97-99, Cookston et al. disclose a deflectable stylet comprising a stylet wire (16) having a plurality of notches (82) and a core wire (18) disposed within a lumen (96) defined by the stylet wire (16) (col. 10, lines 53-67). The core wire (18) has distal portion which is adhesively secured to a section of the stylet wire (16) which is proximate to a distal portion of the stylet wire (16) (col. 7, lines 8-19). The device disclosed by Cookston et al. further includes an adjustable tensioner mechanism (206) which is operably connected to the device for applying a tension force between the stylet wire (16) and the core

wire (18) (col. 13, lines 12-67). The device includes a tension limiter (258) which is operably arranged for limiting the tension force between the core wire (18) and the stylet wire (16). Cookston et al. disclose the device returning to an original position upon removing tension force from the stylet wire (col. 13, lines 45-67; col. 14, lines 1-18). The tension limiter is capable of limiting the tension force on the device to a limit force that is less than the breaking force of the stylet wire (col. 13, lines 12-21). The tension limiter includes a constant force spring (246) which delivers a maximum tensile strength force which is less than the breaking force of the stylet wire (col. 13, lines 12-67; col. 14, lines 1-49). The tensioner limiter mechanism engages with the compressible spring to increase a force opposing movement of the tensioner. The device disclosed by Cookston et al. is shown in Figure 16 below.

Fig. 16



Examiner submits the placement of the tensioner mechanism (206) of the Cookston et al. can be within a housing or external to the housing based on design preference. One of ordinary skill in

the art would reasonably expect a tensioner mechanism designed as Cookston et al. shows to perform equally well if the mechanism is located as shown in Figure 16 or if the mechanism was within a housing of the device. Limiting the access to the mechanism may result in a reduction of undesirable adjustments being made to the tension of the device. Additionally Examiner submits the tension limiter is capable of limiting the tension force whenever the tensioner mechanism is adjusted. There is no indication that there is a suggested frequency of this step, therefore it is reasonable to expect the device to be able to limit the tension force with the tension limiter every time the tensioner mechanism is adjusted. Cookston et al. disclose the features of the Applicant's invention as described above. Cookston et al. do not disclose the spring operably arranged between the adjustable tensioner mechanism and a proximal portion of the stylet wire which is spaced apart from the distal region. Lundquist et al. disclose a steering mechanism including a steering shaft coupled to a controller which includes a handle apparatus for manipulating the distal end of the shaft. The steering shaft has a flexible coiled spring having a lead spring in a fixed position relative to the distal end of the shaft. Lundquist et al. disclose the device including a tension adjusting mechanism which is accessible without disassembling the apparatus and allows adjustment of the tension of the device upon use. The spring of the Lundquist et al. device is attached between the tensioning mechanism and the proximal end of the core wire of the device. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a deflectable stylet comprising a stylet wire having a plurality of notches and a core wire disposed within a lumen defined by the stylet wire, similar to that disclosed by Cookston et al., to include a tensioning adjustment mechanism and a tension limiter connected to the core wire and the tension adjusting mechanism, similar to

that disclosed by Lundquist et al., to allow the device to negotiate tortuous paths without placing too much stress on the body structures (col. 13, lines 25-67; col. 14, lines 1-16).

4. Claims 65 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cookston et al. (U.S. Patent Number 6,132,390) in view of in view of Lundquist et al. (U.S. Patent Number 6,033,378) And in further view of Erickson et al. (U.S. Patent Number 5,755,695).

In regard to claims 65 and 85, Cookston et al. and Lundquist et al. disclose the features of the Applicant's invention as described above. The combined references do not disclose the breaking stress force of the stylet wire being at least 6 pounds and the limit force of the tension limiter being less than 4 pounds. Erickson et al. disclose a medical guidewire having a steering handle for guiding a guidewire and catheter through a vessel of a patient. Erickson discloses the use of a handle which permits the guide wire to be manipulated. The handle uses a gripping force of at least 1 pound to maintain a good connection between the handle and the steerable wire. The handle of the Erickson et al. device is used to apply force to the wire and acts as a tension limiting device. The amount of tension applied to the wire of the Erickson et al. device is limited by the amount of force capable of being applied by the handle. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a deflectable stylet comprising a stylet wire, similar to that disclosed by Cookston et al. and Lundquist et al., to include a limiting force, similar to that disclosed by Erickson et al., to minimize the likelihood of the wire breaking during use.

5. Claims 67-74, 76, 87-94 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cookston et al. (U.S. Patent Number 6,132,390) in view of Lundquist et al.

(U.S. Patent Number 6,033,378) and in further view of Rosenman et al. (U.S. Patent Application Publication Number 2003/0229386).

In regard to claims 67-69, 71-74, 87-89 and 91-94, Cookston et al. and Lundquist et al. disclose the features of the Applicant's invention as described above. Cookston et al. and Lundquist et al. do not specifically disclose information regarding the plurality of notches formed in the distal region of the stylet wire. Rosenman et al. disclose a guide catheter system having a distal tip provided with steering capability. The Rosenman et al. guide catheter system includes slots which are positioned on the distal tip of the device. The slots are arranged into the tube of the distal tip to help control the shape of the distal portion as it bends (paragraph [0025]). Rosenman et al. disclose the slots progressively decreasing in depth from the distal to proximal end of the distal tip. The most distal slots have a diameter approximately equal to the radius of the catheter minus the wall thickness of the catheter. Each slot of the Rosenman et al. device has a longitudinal width of 0.014" and is spaced at a distance of 0.040" from one another. A plurality of separate sets of slots is defined by Rosenman et al. The portion of the slots which decrease in depths comprise between about 5% and about 50% of the slots in the distal tip. Rosenman et al. further disclose a constant decrease in depth between the two adjacent slots that end one set and begin another set (paragraph [0025]). The distance between each set of slots measured from first slot of one set to the first slot of an adjacent set is at least 0.1". Upon defining a set of 10 slots, the set includes a portion of notches having a progressively decreasing depth distally to proximally. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a deflectable stylet comprising a stylet wire, similar to that disclosed by Cookston et al. and Lundquist et al., to include a plurality of notches with a

specific configuration, similar to that disclosed by Rosenman et al., to improve control of the shape of the distal portion of the device.

In regard to claims 70, 76, 90 and 96, the combined references of Cookston et al., Lundquist et al. and Rosenman et al. disclose the features of the Applicant's invention as described above. The combined references do not disclose having three of the most proximal slots having a constant decrease in depth. The combined references also do not disclose having at least two sets of notches having different spacing and widths. Examiner submits as taught by Rosenman et al., it would be desirable to make slots in the distal tip with varying depths to be able to control the shape of the device during use. In effort to better suit the purpose of use, changes such as changing the slot depth dimensions of the device would be obvious variants of the invention as originally taught by Cookston et al., Lundquist et al. and Rosenman et al. Examiner submits, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the dimensions of the slot depths, including having three slots progressively decrease in depth or having a set of slots differ in width and spacing, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

6. Claims 75 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cookston et al. (U.S. Patent Number 6,132,390) in view of Lundquist et al. (U.S. Patent Number 6,033,378) and in further view of Hata et al. (U.S. Patent Number 6,611,720).

In regard to claims 75 and 95, the combined references of Cookston et al. and Lundquist et al. discloses the features of the Applicant's invention as described above. The Cookston et al. and Lundquist et al. references does not specifically disclose including a set of notches at a different

radial position than another set on the distal region of the stylet wire. Hata et al. disclose a deflectable high torque catheter which includes a plurality of staggered rows of slits (col. 3, lines 50-63). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a deflectable stylet comprising a stylet wire, similar to that disclosed by the combined references of Cookston et al. and Lundquist et al., to include a plurality of notches with a specific configuration, similar to that disclosed by Hata et al., to provide multi-directional deflectablility of the distal portion of the device (Hata et al: col. 2, lines 55-64).

Response to Arguments

7. Applicant argues the prior art references fail to disclose the features of Applicant's invention as amended. Specifically, Applicant argues the prior art the does not have a spring to blunt any excessive force and prevent breakage whenever the adjustable tensioner mechanism is adjusted. Examiner submits the prior art does teach having a constant force spring as part of the tension limiter device. The tension limiter is capable of limiting the tension force on the device to a force that is less than the breaking force of the stylet wire (col. 13, lines 12-21). The constant force spring of the tension limiter delivers a maximum tensile strength force which is less than the breaking force of the stylet wire. The tensioner limiter mechanism engages with the compressible spring to increase a force opposing movement of the tensioner. As mentioned above, the arrangement of the spring either within the housing or external to the housing is merely a design consideration and would not make the Applicant's invention patentably distinct from the prior art. One would expect the spring positioned within the housing or outside the

housing to perform the function of limiting the tension force equally well in either location. With the prior art having the same mechanical features, it is reasonable to expect the spring of the prior art device to operate in a manner to blunt any excessive force and prevent breakage whenever the adjustable tensioner mechanism is adjusted as claimed by Applicant. Applicant's arguments filed February 9, 2011 have been fully considered but they are not persuasive. The rejection stands.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FANGEMONIQUE SMITH whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736